RECEIVED AT DRUG SAFETY SURVEILLANCE
19-FEB-1998-0642

McNEIL CONSUMER PROD
FORT WASHINGTON

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Individual Safety Report
3032563-5-00

A. Patient information

1. Patient identifier	2. Age at time of event: / or Date of birth:	3. Sex	4. Weight
Case 214 In confidence	55 yrs	( )female (X)male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

(X) death unknown (mo/day/yr)
( ) life-threatening
(x) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
( ) other:

3. Date of event	4. Date of this report
unknown (mo/day/yr)	02/06/98 (mo/day/yr)

5. Describe event or problem

Case # 214 received from the [redacted] 1996 case fatality data.
See attached case report form provided by [redacted]

6. Relevant tests/laboratory data, including dates

See attached case report form provided by [redacted]

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

See attached case report form provided by [redacted]

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 TYLENOL Analgesic Unknown
#2 ethanol

2. Dose, frequency & route used
#1 "only a couple" per day
#2 unknown

3. Therapy dates (if unknown, give duration) (from/to (or best estimate))
#1 chronic
#2 chronic

4. Diagnosis for use (indication)
#1 chronic rib injury
#2 unknown

5. Event abated after use stopped or dose reduced
#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No (X) N/A

6. Lot # (if known)
#1 Unknown
#2 unknown

7. Exp. date (if known)
#1 Unknown
#2 unknown

8. Event reappeared after reintroduction
#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No (X) N/A

9. NDC # - for product problems only (if known)
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)
See attached case report form provided by [redacted]

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)
McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number
215-233-7820

3. Report source (check all that apply)
( ) foreign
( ) study
(x) literature
( ) consumer
(x) health professional
( ) user facility
( ) company representative
( ) distributor
( ) other:

4. Date received by manufacturer (mo/day/yr)
01/30/98

5.
(A) NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)
( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
(X) Initial ( ) follow-up #

8. Adverse event term(s)
SGOT INCREASED
BILIRUBINEMIA
PROTHROMBIN INC
CONFUSION
RESPIRATORY DIS
BUN INCREASED
CREATININE INC
DEATH

9. Mfr. report number
0929932A

E. Initial reporter

1. Name, address & phone #
[redacted] MD
[redacted] Centers
[redacted] Avenue
[redacted]

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes ( ) No	physician	( ) Yes ( ) No (X) Unk

FDA
Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

[redacted] TESS FATALITY: 1996 [redacted]

Case Number:	**214**
Age:	55 yrs
Substances:	Acetaminophen ethanol
Chronicity:	Chronic
Route:	Ingestion
Reason:	Ther error
Pre-Hospital Arrest?	No

The patient was a 55 year old male with a history of cirrhosis and chronic ethanol abuse. He had reportedly been taking "only a couple of Tylenol" a day for a chronic rib injury. He was admitted to the hospital for jaundice and found to have an AST of 4000 IU/l, total bilirubin of 7.7mg/dl, and a prothrombin time of 22 seconds after receiving vitamin K. He was started on n-acetylcysteine and received a total of 18 doses orally. The patient also had a normal gall bladder ultrasound. The patient became increasing confused and developed pulmonary infiltrates. ...e was started on lactulose and furosemide and fed through a NG tube. His bilirubin peaked at 34.6 mg/dl and his BUN rose to 72 mg/dl with a creatinine of 3.6 mg/dl with a normal AST. The patient was made DNR and died on 3/17/96.